to coordinate AIDS Control activity in the country.

(2) 34 surveillance centres have been established in the country to screen high risk group.

(3) All these centres have been provided with diagnostic reagents and equipment package have also been provided to most of them.

(4) Restrictions have been imposed for import of blood and blood products without AIDS clearance certificate.

(5) All the State Health Authorities Hospitals STD clinics have been alerted to be vigilant.

(6) All the blood banks have been instructed to screen the professional blood doners.

(7) All the State Health Authorities have been advised to ensure strict sterilisation practices in hospitals and clinics, and to use pre-sterilised disposable syringes and needles as far as possible.

(8) Guidelines have been sent to all the State Health Authorities for Health care personnel.

(9) All the mass media channels have been involved in educating the people on AIDS, its nature, transmission and prevention.

(10) Foreigners other than those working in Missions including foreign students likely to stay in India for more than one year will be required to undergo AIDS test on arrival. However, foreign students who are already in India when admission is sought will not be required to undergo AIDS test.

Guidelines for New Drugs, Vaccines and Combinations

510. SHRI BHUBANESWAR KALITA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Government have issued guidelines defining new drugs, new vaccines and combination of one or more drugs;

(b) if so, what are the details of the same;

(c) whether it is a fact that according to these guidelines the States Drugs Authorities are not authorised to issue any permission for new drugs, new vaccines and new combination of drugs and vaccines;

(d) names of new drugs, new vaccines and new combination of drugs and vaccine allowed by each State Drug Authorities from 1st April, 1986 to 30th June, 1987;

(e) what are the basis on which these permissions have been granted;

(f) whether it is a fact that neither any clinical trial nor any published data was submitted; and

(g) what steps have been taken to suspend the marketing of these products till Government are satisfy about safety, efficiency and other aspects?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) Yes, Sir.

(b) In the guidelines what constitutes a new drug has been defined, the details of pre-clinical data required for granting clinical trial permission in the country have been enumerated, the details of data required for granting marketing permission of a new drug in the country have been given and the various formalities and rules pertaining to import and manufacture of new drugs in the country have been quoted from the Drugs and Cosmetics Act.

(c) to (f) Since the guidelines are not yet statutory some State Drug Control Authorities in consultation with their local experts licence combinations of already marketed drugs and vaccines as they did not strictly consider such combination as new drugs.

The names of combination of drugs and vaccines licensed for marketing by the State Licensing Authorities as avail-

able with the Govt. is given in the annexed statement. ((See below)

(g) Government has initiated steps to make the guidelines on introduction of new drugs including the definition of the terms 'new' drug as statutory. The combinations cleared by the State Licensing Authorities will be reviewed by a sub-committee constituted by the Government to advise Government on the continued marketing of formulations including combinations moving in the Indian market on the basis of safety, efficacy and rationality.

Statement

Combination of drugs cleared by the state drugs control Authorities

S. No.	Name of the product	Composition
1	Arthril Capsules	Kotoprogen B.P. Propyphenazone B.p.
2	Tersiphyl Tablets	Terbyutaline Sulphate B.P. Hydexythul theph:lline I.P., Grain Phenazen B.P.C.
3	Ketodol Capsule	Paracetamol I.P. Ketoprofen B.P.
4.	Tencchetic 50 Tablets	Atenolol U.S.P. Chlorthalidene U.S.P.
5	Golgesic Tablets	Ibuprofen B.P. Analgin I.P.
6.	Promagesic Tablets	Ibuprofen B.P. Mefenamic Acid B.P.
7	Antakid forte Tablets	Magaldrate U.S.P. Simethicome U.S.P.
8	Terbutaline Sulphate with Etofyline Tablets 'Torphylin Forte'	Terbutaline Sulphate Etofyline B.P.
9	Terbutaline Sulphate with Taiameinolone Tablets	Terbutalline Sulphate B.P. Triamerinolone U.S.P. Colour : Sunset Yellow PCF
10	Calmpain-S	Dicyclomine Hcl. B.P. Mefanimic Acid B.P.
11	Veraptim-L Tablets	Verapemil Hydrochloride B.P. Lorazepam
12	Tromaril-P Tablets	Enfemamic Acid Paracetamol I.P.
13	Torhexin Tablets	Torbutaline Sulphate B.P. Bromhaxin Hydrochloride B.P.
14	Bactal (Tablets of Tinidazole and Covtrimoxazole)	Tinidazole I.P. Trimethoprim B. P. Sulphamethaxazole S.P.
15	Hexabutol Tablets	Ethambutal HCI. I.P. Dsoriazid I.P. Vit. B 6 I.P.
16	Meftalab Tablets	Mefamamic Acid B.P. Chlormezenon
17	Repress Tablets	Metroprolol Tertrate Hydrochlonotheuide
18	Fluzyme Ointment	Fluecinelone Acctenoide B.P. Neamcin Sulphate I.P. Tripsin and Chymetrypcin concentrate Equl. to tryptic activity to 4 mg. of Trypsin U SF

S. No.	Name of the product	Composition
19	Inzol Tablets	Indepamide Metroprolol Tartrate USP
20	Silverex Cream	Silver Sulphediazine Chlorhaxadine Gluconate BPC
21	Relaxdol Tablets	Mefanamic Acid B.P. Diamepan I.P.
22	Relaxccol Forte Tablets	Mafonamic Acid B.P. Diaxepam I.P.
23	Imibutanol DS Tablets	Ethambutal Hcl. B.P. Isonlaid I.P.
24	Clonithan Tablets	Clonidine HcL B.P. Chlorthelidone I.P.

The House then adjourned at one minute past three of clock till eleven of the clock on Thursday, the 30th July, 1987.